REMARKS

The Office Action dated June 8, 2007 has been carefully considered. Applicant notes that previously-allowed 6 and 16-20 have now been rejected and that the allowance of those claims has been withdrawn.

Claims 1-8 and 10-13 have been rejected as obvious over Kuslich Publication No. 2002/0077701 (which has now issued as Patent No. 6,712,853) in view of Wedeen Patent No. 4,606,335. Claim 1 has been amended to recast it in "Jepson" form and has further been amended such that the recitation of a "band" for use in treating a spinal disc has been clarified by stating that the band has a height of at least that of a spinal disc to be treated.

These amendments further distinguish claims 1-8 and 10-13 from the cited prior art. As held in Rowe v. Dror, 112 F.3d 473, 42 USPQ 2d 1550 (Fed. Cir. 1997), it is settled law that when a claim is written in this form, the preamble is a structural limitation in the claim. Thus, in order for a combination of references to be a proper basis for rejecting the claims, there must be some basis in either the prior art itself or in the generally accepted skill of the art for combining the references. Here, the rejection is based on Kuslich, which does disclose a band which can be deployed in the interior of the annular fibrosis of the spine, with the totally unrelated Wedeen patent, which is directed to a highly specialized wire passer which has nothing to do with treating spines and is directed to deploying a wire around the exterior of a bone, the exact opposite of the Kuslich procedure in which a band is installed in the interior of a spinal structure. The distinction between the different arts to which Kuslich and Wedeen are directed is apparent from the respective classification and fields of search which appear on the face of each patent. The Wedeen device is classified in Class 128, Subclass 92 and both the cross reference classifications and the field of search are all in Class 128. In marked contrast, Kuslich is classified in Class 623, Subclass 17.16 and the cross reference classification and field of search are in Classes 623 and 606. In addition, and more importantly, the Kuslich reference itself makes it plain why these references are not combinable. As stated in paragraph 60 of Kuslich, the method of using the band of Kuslich is:

> "To state the process in another way: the invention provides a pliable implant that may be inserted into a cavity formed in a degenerating disc."

Thus, the band of Kuslich **into** a cavity in the spinal structure from which material comprising a damaged disc has been removed and is positioned to contain film material which will be used to replace the disc material which has been removed. This is further made plain in paragraph 58 where it is stated that:

> "The band would be flexible enough to fit through a small hole made in the annulus, such as during a routine disc hernia removal operation."

And, again, in paragraph 59 where it is stated:

> "The properly sized band would be pushed through the disc portal, whereupon, owing to its inherent springiness or as a result of the material being injected in the interior of the disc, the hoop or band would expand radially against the outer annulus."

This type of deployment is the direct antithesis of the use of the device of the present invention which is designed for deploying a band **around the outside** of the annulus, **not** for lining the inside of a cavity. The importance of this fact is, of course, that Kuslich has **no need** for any type of deployment device and attempting to combine the wire passer of Wedeen with the spinal band of Kuslich would make absolutely no sense. It is respectfully submitted that it can be said without reservation that it would be readily apparent to those skilled in the art that the devices of Kuslich, designed for an interior lining in a spinal structure, and Wedeen, designed to pass a wire around the outside of a bone, have absolutely nothing in common.

Furthermore, the wire of Wedeen would, if some how used in the procedure of Kuslich, raise a serious risk of damaging the spinal structure by puncturing or breaking some part of the spine.

To restate, the device of Wedeen would have absolutely no use in the proposed combination with Kuslich and any attempt to combine these references would be contrary to the teachings of both. Thus, the rejection is plainly in error and it is respectfully requested that it be withdrawn.

In addition, and not surprisingly, dependent claims 2-8 and 10-13 are also patentably distinct from the combination of Kuslich and Wedeen for separate and independent reasons.

Claim 2 recites a connector element which comprises a hook on the distal end of the elongate member. The wire passer of Wedeen has no such connector, but rather discloses that eyelet 16 is the connector element for the wire to be passed.

Claim 3 recites an opening in the band for receiving the hook. Kuslich has no such opening and Wedeen has no such hook.

Claim 4 recites that the height of the band is sufficient to cover a spinal disc and at least partially cover at least one vertebrae adjacent the spinal disc. The band of Kuslich must be deployed inside the space previously occupied by spinal disc material and cannot be larger than that space.

Claims 5 and 6 recite that the band comprises healing-promoting material and comprises an extra-cellular matrix material, respectively. The Examiner suggests that such disclosures can be found in Kuslich but no such disclosure can be found. The hydroxyapatite referred to by the Examiner is, as disclosed in paragraph 98, a **fill material, not** a part of the band as recited in claim 5 nor is it an extra-cellular matrix material on at least one side of the band as recited in claim 6.

Claim 7 recites a non-porous band. The Examiner states that Kuslich discloses such a band, but Applicant finds no disclosure of that sort in Kuslich.

Claims 12 and 13 recite that a portion of the band is electrically conductive and that a source of electrical energy is coupled to the electrically conductive portion, respectively. The Examiner asserts that such disclosure can be found in Kuslich, but Applicant is unable to find any such disclosure.

Claims 1-8, 10-13 and 16-20 have also been rejected as unpatentable over Kuslich in view of Kaladelfos Patent No. 6,494,887. Kaladelfos is directed to a suturing device which is nothing more than a hollow curved needle through which a suture may be passed. This reference cannot be properly combined with the Kuslich reference any more than Wedeen could be. There is absolutely no need for such a suturing device with regard to the deployment of the band of Kuslich and the Examiner suggests no reason why there might be. One skilled in the art would view the use of a surgical needle to be utterly inappropriate with regard to the band of Kuslich which is intended to be "inserted into a cavity formed in a degenerating disc" as set forth in paragraph 60 of Kuslich. The

use of the needle of Kaladelfos would also be dangerous if an attempt were made to use it in the spine for the same reasons that use of the wire of Wedeen would be dangerous.

Furthermore, the dependent claims are independently patentably distinct from this combination of references for the same reasons as those set forth above with regard to the combination of Kuslich and Wedeen.

Claim 16 has been rewritten as independent claim 23 and claims 24-26 depend from claim 23. These claims add an additional element to those recited in claim 1, namely, a "guide member", the guide member having a lumen for receiving the band. Kuslich has absolutely no need or use for such a guide member to deploy his band through a hole in the annulus fibrosis and Kaladelfos cannot be properly combined with Kuslich for that reason. In addition, the structure of Kaladelfos completely lacks any "elongate member comprising a proximal end including a handle and a curved distal end including a connector element" as recited in claim 23 (and claim 1 as well). Furthermore, contrary to the teaching of the present invention, Kaladelfos has no elongate member to facilitate the threading of the suture through the hollow curved needle, bur rather simply threads the suture by hand. Thus, even if combined in some manner, the combination of Kuslich and Kaladelfos would fail to teach the claimed invention because neither discloses, nor has any need for, the elongate element 12 of Applicant which has curved distal end 30.

Claim 27 (formerly claim 20) not only recites the elongate member which is missing from the references, it also recites "a pair of opposite-hand guide members" which are not, contrary to the Examiner's assertion, mere duplication of the essential working parts of a device. Rather, these opposite-hand guide members are cooperating elements which are entirely distinct from the single suture passing needle of Kaladelfos.

Claims 14 and 15 have been rewritten in independent form and it is understood that these claims are considered to be allowable.

It is respectfully submitted that the claims of the present application are patentably distinct from the references of record and a favorable action is respectfully solicited.

The Commissioner is authorized to charge Orrick Herrington & Sutcliffe's Deposit Account No. **150665** in the amount of **$230.00** for the two month extension fee. The Commissioner is authorized to charge any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. **150665.**

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Respectfully submitted,

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